UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,578	01/30/2004	Robert G. Lowery	112520.00004	8954

7590 03/19/2007

Sara D. Vinarov
Quarles & Brady LLP
P O Box 2113
Madison, WI 53701-2113

EXAMINER	
STAPLES, MARK	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,578	LOWERY ET AL.	
	Examiner	Art Unit	
	Mark Staples	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/03/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-29* is/are pending in the application.

4a) Of the above claim(s) *3, 4, 16-18 and 25-27* is/are withdrawn from consideration.

5)☒ Claim(s) *28 and 29* is/are allowed.

6)☒ Claim(s) *1,2,5-15,19-21,23 and 24* is/are rejected.

7)☒ Claim(s) *22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20061025, 20061221* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment of 1, 5, 6, 19, 23, 28, and 29; cancellation of claims 3 and 4; and withdrawal of claims 16-18 and 25-27 in the paper filed on 01/03/2007 is acknowledged. The Declaration of Robert Lowry under 37 CFR 1.132 filed on 01/02/2007 is also acknowledged.

Claims 1, 2, 5-15, 19-24, 28, and 29 are pending and at issue.

Applicants' arguments filed on 01/03/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections that are Withdrawn / Moot

2. The objection to the specification is withdrawn in light of the Applicant's amendment of the specification.

Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph

3. The claim rejections under 35 USC § 112 Second Paragraph are withdrawn in light of the Applicant's amendment of the claims.

Claim Rejections Moot - 35 USC § 103(a)

4. Applicant's arguments with respect to claims 3 and 4 are moot in view of the Applicant's cancellation of these claims. The rejections of these claims are likewise moot.

5. Applicant's arguments with respect to claims 1-2, 7-10, 12-15, 19-21, 23 and 24 have been considered but are moot in view of the new ground(s) of rejection. The rejections of claims 1-2, 7-10, 12-15, 19-21, 23 and 24 under USC 103(a) are moot in light of Applicant's amendment of claim 1 to recite "an antibody". These claims were rejected as being unpatentable over Seethala (2000) in view of either Li et al. (2000) or Glassler et al. (2001). The new rejections are given below.

6. Applicant's arguments with respect to claims 5, 6, and 11 have been considered but are moot in view of the new ground(s) of rejection. These claims were rejected over Seethala (2000) in view of either Li et al. (2000) or Glassler et al. (2001) as applied to claims 1-2, 7-10, 12-15, 19-21, 23 and 24 above, and further in view of Bredehorst (1978) and in further view of Kawamitsu et al. (1984). The basis of these rejections was the partial differentiation of ATP from ADP by an antibody specific to AMP as taught by Bredehorst. This partial differentiation is found not to be obvious for arriving at the instant claimed invention in light of the two documents filed on 01/03/2007, the Declaration of Robert Lowry and Applicant's arguments in the response beginning on page 16 the 1st paragraph through to the 2nd paragraph of page 18, in parts. However Bredehorst does teach the differentiation of AMP from ADP by an antibody and this forms the basis of new rejections of claims 5, 6 and 11, given below.

Claim Rejections Withdrawn - 35 USC § 103(a)

7. Applicant's arguments, see the response beginning in 1st paragraph of page 16 through to the 2nd paragraph of page 18 (in the parts pertaining to differentiation of ADP from ATP by an ADP specific antibody) and the Declaration of Robert Lowry under 37 CFR 1.132 both filed on 01/02/2007, with respect to claims 22, 28, and 29 have been fully considered and are persuasive. The rejections of claims 22, 28, and 29 under USC 103(a) have been withdrawn.

Double Patenting Rejection Withdrawn

8. The provisional obvious-type double patenting rejection is withdrawn in light of Applicants withdrawal, on the file date of 02/21/2007, of claims 8-16 and 18 of Copending Application No. 11/353,500.

Should Applicant re-instate claims 8-16 and 18 of Copending Application No. 11/353,500 or file a new related copending application, or have other related copending applications, Applicant is requested to comply with 37 CFR 1.56 by identification of those related copending applications and providing a copy of the current version of claims pending in the those applications that are particularly close to issuance, which raise double patenting issues.

New Objections Necessitated by Amendment

New Claim Rejections - 35 USC § 103(a)

9. Claims 1-2, 7-10, 12-15, 19-21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seethala (2000), either Li et al. (2000) or Glassler et al. (2001), and Bredehorst et al.

Applicant has amended claim 1 to recite "an antibody" instead of a macromolecule which necessitated the combination of these teaching in rejection of claim 1 and dependent claims. For this new rejection, it is not necessary to introduce any new teaching of Seethala, Li et al., and Glassler et al. not previously brought forth in the prior Office Action mailed on 10/02/2006.

Seethala, Li et al., and Glassler et al teach as noted in the prior Office Action.

Bredehorst et al. teach production of antibodies against ADP-ribose and AMP (see Title). Bredehorst et al. teach how design of the immunogen can lead to desired specificity for AMP. Bredehorst et al. further teach an antibody which recognizes 5'-AMP a nucleotide and a donor-product through a relative binding affinity of 100, and does not recognize 5'-ADP the donor molecule by virtue of a weak relative binding affinity of 1.6 (entire reference, especially Table 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Seethala and either Li et al. or Glasser et al. to use an antibody as taught by Bredehorst et al. which binds to the donor product, AMP, with a reasonable expectation of success. The motivation to

do so is provided by Bredehorst who teach that that antibodies specific to AMP can be produced for quantification of AMP over ADP. Bredehorst et al. further teach strategies for arriving at a desired antibody specificity for AMP. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Applicant's arguments filed 01/03/2007 have been fully considered but they are not persuasive. Applicant initially argues that the cited prior art is directed to the specie of kinases, a type of enzyme, whereas certain claims of the instant application recite the broader, more universal, genus of enzymes. However "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus" (see MPEP § 2131.02) and thus the prior art citations to kinases are correctly applied in rejections of the generic claims reciting enzymes.

In response to applicant's argument on pages 13 and 14 that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Li et al. and Gassler et al. are not relied upon to cure the alleged deficiencies of (1) detection of donor product such as ADP, (2) a competitive binding

assay, or (3) an antibody. As noted in the prior Office Action mailed on 10/02/2006, Seethala is relied upon for the obviousness of these three elements.

In response to applicant's argument on page 15 that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "ADP immunodetection" and "detection of . . . ADP in the presence of ATP") are not recited in rejected claims 1-2, 7-10, 12-15, 19-21, 23 and 24. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues on page 15 that Examiner admits to certain deficiencies in Seethala which is the lack of teaching a specific assay configuration where the tag is coupled to the donor product, ADP. However, Seethala is not relied upon to cure this alleged deficiency, Li et al. are relied upon to cure this deficiency.

Applicant further argues on page 16 that Examiner admits to certain deficiencies in Li et al which is the lack of teaching an antibody. However, Li et al. is not relied upon to cure this alleged deficiency, Bredehorst is relied upon to cure this deficiency.

Applicant argues in the response on pages 16 and 17 that Bredehorst does not teach the differentiation of ATP from ADP. This argument is not found persuasive to overcome the rejection of claims 1-2, 7-10, 12-15, 19-21, 23 and 24, as these claims also read on the differentiation of ADP from AMP which Bredehorst does teach as noted above.

In response to applicant's argument at the top of page 17 that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "distinct tracer structures that proved successful") are not recited in rejected claims 1-2, 7-10, 12-15, 19-21, 23 and 24. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. Claims 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seethala (2000), either Li et al. (2000) or Glassler et al. (2001), and Bredehorst et al. (1978).

Applicant's arguments filed 01/03/2007 have been fully considered but they are not persuasive. The same rejections as given in the previous rejection apply here as Applicant has not argued against the rejection of the elements of claims 6 and 11 but rather argues against the rejection of the elements in claim 1. The rejection of claim 1 is maintained. Examiner has made this separate section for claims 6 and 11 for ease of reference.

Repeated from above:

Seethala, Li et al., and Glassler et al teach as noted in the prior Office Action.

Bredehorst et al. teach production of antibodies against ADP-ribose and AMP (see Title). Bredehorst et al. teach how design of the immunogen can lead to desired specificity for AMP. Bredehorst et al. further teach an antibody which recognizes 5'-AMP a nucleotide and a donor-product through a relative binding affinity of 100, and

does not recognize 5'-ADP the donor molecule by virtue of a weak relative binding affinity of 1.6 (entire reference, especially Table 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Seethala and either Li et al. or Glasser et al. to use an antibody as taught by Bredehorst et al. which binds to the donor product, AMP, with a reasonable expectation of success. The motivation to do so is provided by Bredehorst who teach that that antibodies specific to AMP can be produced for quantification of AMP over ADP. Bredehorst et al. further teach strategies for arriving at a desired antibody specificity for AMP. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Applicant argues again in the response of the last paragraph on pages 17 through the entire page 18 that Bredehorst does not teach the differentiation of ATP from ADP. This argument is not found persuasive to overcome the rejection of claims 6 and 11, as these claims also read on the differentiation of ADP from AMP which Bredehorst does teach as noted above.

In response to applicant's argument in the last paragraph on page 18 that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's

disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

11. Claims 5, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seethala (2000), either Li et al. (2000) or Glassler et al. (2001), and Bredehorst et al. as applied to claims 1 and 10 above, and further in view of Kawamitsu et al. (1984).

Applicant's arguments filed 01/03/2007 have been fully considered but they are not persuasive.

Seethala, Li et al., Glassler et al., and Bredehorst teach as noted above.

Seethala, Li et al., Glassler et al., and Bredehorst do not specifically teach a monoclonal antibody to a donor product such as ADP.

Kawamitsu et al. teach monoclonal antibodies which bind to poly adenosine diphosphate (poly(ADP-Rib) and to the monomer unit, Ado(p)-Rib-P, a nucleotide and donor-product from the diphosphate. A monoclonal antibody is a species of antibody. Kawamitsu et al. also teach how design of the immunogen and selection of clones can lead to a monoclonal antibody of desired specificity.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Seethala and either Li et al. or Glasser et al. and Bredehorst to use a monoclonal antibody as taught by Kawamitsu which binds to the donor product with a reasonable expectation of success. This method is a fluorescence polarization immunoassay (FPIA). The motivation to do use this approach is provided by Kawamitsu et al. who teach that that antibodies to

Ado(p)-Rib-P can be successfully produced for detection of Ado(p)-Rib-P. Kawamitsu et al. further teach strategies for arriving at a desired antibody specificity. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

In response to applicant's argument on page 19 that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "antibodies that selectively recognize ADP in the presence of ATP" and "mononucleotide") are not recited in rejected claims 5, 6, and 11. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, the nucleotide polymers and monomers of Kawamitsu et al. are nucleotides and thus read on claims 1, 5, 6, 10, and 11 as written, with the recital of "nucleotide" in claim 1. There is no limitation in these claims that donor or donor product be a mononucleotide. Furthermore, the specification does not define a nucleotide as a mononucleotide. The specification even discloses use of di-nucleotides (for example, see paragraph 0015).

Allowable Subject Matter

12. Claims 28 and 29 are allowed.

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 22 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 28. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

As conveyed in the Declaration of Robert Lowry under 37 CFR 1.132 filed on 01/02/2007, the prior art does not teach or fairly suggest the detection of the donor product ADP by an antibody specific to ADP, in the presence of the donor ATP.

Conclusion

13. Claims 28 and 29 are allowed.

14. Claim 22 is objected to.

15. Claims 1-15, 19-22, 23, and 24 are not free of the prior art.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
March 14, 2007

MS

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
3/15/07